

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 17VV-137270
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>	Application Number 09/927,914	Filed August 10, 2001
	First Named Inventor Timothy P. Tully	
	Art Unit 1617	Examiner Yong Soo Chong
	<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>	
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. <u>33754</u> Registration number _____.</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>		
<p></p> <p>Signature</p> <p>Don J. Pelto</p> <p>Typed or printed name</p> <p>202-218-0000</p> <p>Telephone number</p> <p>January 30, 2009</p> <p>Date</p>		
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>		
<p><input checked="" type="checkbox"/> *Total of <u>4</u> forms are submitted.</p>		

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	09/927,914	Confirmation No. 5180
Applicant	Timothy P. Tully <i>et al.</i>	
Filed	August 10, 2001	
TC/Art Unit	1617	
Examiner	Yong Soo Chong	
Docket No.	17VV-137270	
Customer No.	68850	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314
MAIL STOP AF

Sir:

Applicants respectfully request review of the final rejection in the above-identified application. No amendments are being filed with this request.

This Pre-Appeal Brief Request for Review is being filed concurrently with a Notice of Appeal and is submitted for the reasons stated on the attached sheets.

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks. Claims 1, 4-8, 14, 16-20, 49, 51-57, 60-64, 98 and 100-114 are currently pending in the application.

Introduction

The Examiner's Advisory Action, dated December 1, 2008 maintained a single rejection of Claims 1, 4-8, 14, 16-20, 49, 51-57, 60-64, 98 and 100-104 under 35 U.S.C. § 103 as obvious over United States Patent Number 5,547,979 ("Christensen") in view of the Merck Manual. In this Pre Appeal Request for Review, Applicants challenge the propriety of this rejection.

The Examiner's Obviousness Rejection is Clearly Erroneous Because It Improperly Uses the Inherency Doctrine

In the Final Office Action mailed on Sept. 30, 2008 ("FOA"), the Examiner maintained the present obviousness rejection, in part, based upon certain disclosures deemed to be "inherent" in the cited art. In its response to that Final Office Action, Applicants specifically challenged the Examiner's use of the inherency doctrine in two instances. Response dated Dec. 1, 2008, at 15-16. In the Advisory Action mailed on December 15, 2008, the Examiner rejected those arguments:

[Applicants' argument] is not persuasive because Applicant still does not understand the inherency argument was not used to support the motivation in the obviousness rejection. Applicant's disclosure was merely used to show that the term "performance gain of a cognitive task" can be interpreted to cover a wide range of impairments, which overlap the teachings of the prior art.

Advisory Action at 2. This response by the Examiner is inadequate factually and legally.

The Examiner's use of inherency is far broader than that set forth in the Advisory Action. In the OA, the Examiner used inherency in two respects. First, the Examiner argued that since Applicants' disclosure shows that rolipram is a phosphodiesterase inhibitor, that Christensen inherently discloses "administering a phosphodiesterase inhibitor." FOA at 6. Second, the Examiner argues that the claim limitations of "which enhances CREB pathway function" and "wherein rehabilitation of said cognitive deficit is effect by producing a long lasting performance

gain" are given little patentable weight because these biological processes are inherent when the same compound is administered in the same patient population at the same dosage. OA at 3-4.¹

Each of the Examiner's uses of inherency is clearly erroneous. Inherency has only a very limited use in obviousness rejections. This is because "[t]hat which may be inherent is not necessarily known" and "[o]bviousness cannot be predicated on what is unknown." *Application of Shetty*, 566 F.2d 81 (C.C.P.A. 1977); *see also* MPEP § 2141.02 ("Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established (citing *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993)).² Stated differently, obviousness is based upon what the references disclose to one of ordinary skill in the art at the time of filing. The Examiner must demonstrate that rolipram was well-known in the art as a phosphodiesterase 4 inhibitor prior to Applicants' filing date. The Examiner must also demonstrate that it was well-known in the art that rolipram "enhances CREB pathway function" and that rolipram in conjunction with the cognitive training "produc[es] a long-lasting performance gain." Quite clearly, the Applicants' disclosure cannot be an appropriate source of that information. Thus, to the extent the Examiner relies on a theory of inherency to support the outstanding 35 U.S.C. § 103, such reliance is improper.

¹ *See also* OA at 4 ("Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present.").

² Other cases echo this statement of the law. *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989) (reversing an examiner's obviousness rejection because "a retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination"); *see also id.* ("It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." (internal quotations omitted)); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1576 (Fed. Cir. 1986) (affirming lower court's holding of nonobvious where it was "unidisputed" that a prior art product inherently had one of the claimed elements, but where the defendant "fail[ed] to establish at trial that that inherency would have been obvious to those skilled in the art when the invention [] was made"); *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966) ("[T]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on that which is unknown.").

In short, the Examiner's rejection is clearly erroneous because a reference (Christensen) that does not recite or in any way teach or suggest phosphodiesterase 4 or the CREB pathway simply cannot disclose or fairly suggest the treatment of a cognitive disorder by inhibiting phosphodiesterase 4 in order to enhance CREB pathway, as Applicants currently teach and claim. Neither Christensen nor the Merck Manual, either alone or in combination, provides any teaching or suggestion of a beneficial link between the inhibition of phosphodiesterases and cognitive training. Therefore, these references, singly or in combination, do not teach or suggest all of the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

Conclusion

In light of the foregoing and for all those reasons in Applicants' various responses of record, including those dated February 6, 2008 and December 1, 2008, Applicants respectfully request that the Panel re-open prosecution on the merits or withdraw the rejections of record and allow the claims as presently drafted. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

January 30, 2009



Don J. Pelto
Reg. No. 33,754

Sheppard Mullin Richter & Hampton, LLP
1300 I Street NW, 11th Floor East
Washington, DC 20005
Telephone: (202) 218-0000
Facsimile: (202) 218-0020